

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

Donna Wright, individually and on behalf of
all others similarly situated,

Plaintiff,

- against -

Dollar General Corporation,

Defendant

5:23-cv-646 (FJS/ML)

Class Action Complaint

Jury Trial Demanded

Plaintiff alleges upon information and belief, except for allegations about Plaintiff, which are based on personal knowledge:

1. Dollar General Corporation (“Defendant”) sells adhesive patches promising to deliver 4% lidocaine under the DG Health brand (“Product”).



2. The representations include its description as a “Maximum Strength” “Lidocaine Pain Relief Gel Patch” delivering “Lidocaine 4% [as a] Topical Anesthetic,” and invites purchasers to “Compare [it] to the active ingredient of Salonpas Lidocaine 4% Pain Relieving Gel-Patch*.”

3. The label indicates it provides “Numbing relief” that is “Fast-acting” through a “Stay-put flexible patch” that “Lasts Up To 12 Hours,” displayed in rifle sights, to the “Neck, Shoulder, Back, Knee & Elbow.”

4. Next to these statements is a humanoid figure with heat concentration spots on the neck, back, shoulders and elbows, from a patch applied to the lower back, giving the purchaser the impression that applying a patch to one area of the body will numb pain in other areas of the body.

I. LIDOCAINE BACKGROUND

5. Lidocaine is a topical anesthetic used to treat pain by blocking the transmission of pain signals from nerve endings in the skin to the spinal cord and brain.

6. In 1983, the Food and Drug Administration (“FDA”) issued requirements for the labeling, ingredients, uses, and doses of external analgesic products, allowing the use of lidocaine at 4% in the form of an ointment.

7. New York has adopted the identical FDA regulations pertaining to the labeling of lidocaine patches.

8. The first lidocaine patch required a prescription and was approved in 1999 to help reduce pain associated with post-herpetic neuralgia (“PHN”), a complication of shingles.

9. In 2003, the FDA began reviewing over-the-counter (“OTC”) lidocaine patches to determine the safe and effective concentration of this ingredient in this format.

10. Doctors discovered that lidocaine patches are effective in treating general neuropathic pain like muscle and spinal aches and began prescribing the patches off-label.

11. A 2012 study found that over 82% of the usage of prescription lidocaine patches were off-label.

12. As the use of lidocaine patches increased, national brands such as Salonpas and Aspercreme spent significant amounts of money to advertise their over-the-counter (“OTC”) patches as equivalent to those available only with a prescription.

13. In 2013, the FDA concluded that lidocaine patches were not “generally recognized as safe and effective” for OTC use because there was insufficient information about how often the plaster or poultice needed to be changed.

II. PRODUCT FAILS TO DELIVER LIDOCAINE IN PROMISED WAY DUE TO ADHESION DEFECTS

A. How Lidocaine Patches Work

14. Lidocaine patches use transdermal/topical delivery systems (“TDS”), which have three main parts: (1) an outer protective backing membrane, (2) a drug-in-adhesive (“DIA”) layer, and (3) a release liner that controls the rate and extent of drug administration.

15. Since the FDA did not contemplate the delivery of lidocaine in patch form, their strength cannot be evaluated based on the previously issued guidance.

16. Manufacturers of lidocaine patches like Defendant attempt to meet the FDA’s 4% benchmark based on the mass of drug relative to the mass of the adhesive per patch.

17. However, the amount of lidocaine contained in, or delivered by, a lidocaine patch cannot be determined based on the arbitrary measure of a patch’s drug-to-adhesive ratio.

18. This allows Defendant to alter the total mass of lidocaine in the Product by adjusting the thickness of its back membrane without changing its dimensions.

19. The result is that purchasers and doctors are misled by the Product’s drug-to-adhesive ratio, because they expect the percentage of an active ingredient has a direct correlation to the

quantity, or efficacy, of that ingredient within the delivery mechanism.

B. Adhesion Failure Defects

20. Since adequate adhesion is critical to delivery in the form of a patch, any lifting or detaching while walking, sleeping or exercising will compromise dosing.

21. The FDA Adverse Events Reporting System (“AERS”) revealed that approximately 70% of consumer complaints about such products, including upon information and belief, Defendant’s Product, relate to their poor adhesion.

22. The FDA concluded that because the patches systemically fail to adhere to the body, they cannot provide the claimed pain relief.

23. This is in line with complaints made by purchasers of the Product to Defendant about its lack of adhesion abilities, through its online website, telephone, and other methods.

24. A January 2021 peer-reviewed study by the Journal of Pain Research analyzed store brand or private label lidocaine patches, substantially similar and/or identical to the DG Health lidocaine patch, and concluded that none of them exceeded ninety percent adhesion within the twelve-hour testing period.

25. Rather, their average adhesion after twelve hours was less than forty percent.

26. This was based on a scale where zero reflected complete detachment and fifty percent meant half the patch lifted off the skin but did not fully detach.

27. These findings understated the poor adhesion qualities of private label lidocaine patches, because study participants were required to remain sedentary during the time the patches were applied, whereas typical users will be walking, exercising, sleeping and otherwise attempting to function normally.

28. Although the study tested generic lidocaine patches, a comparison between the

samples analyzed and Defendant's Product reveals they both use the same defective adhesion technology, which has not undergone the rigorous FDA approval process.

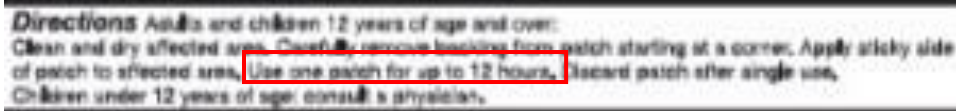
29. Though other companies have innovated their technology based on clinical studies to ensure their lidocaine patches are sufficiently flexible to adhere to a user's body during walking, sleeping, exercising and other everyday activity, upon information and belief, Defendant has not.

30. This is crucial because "[a]dequate adhesion is a critical quality attribute for topical delivery systems; if the product lifts or detaches during wear, dosing may be compromised and there is an increased risk of inadvertent exposure to others."

31. Since the Product cannot adhere to a person's skin throughout the promised time period, it cannot deliver the active anesthetic ingredient of lidocaine during that time.

32. When consumers see the promise of "LASTS UP TO 12 HOURS" providing "Numbing relief" in the form of a "Stay-put flexible patch," they will expect the Product will adhere to their bodies for close to or no less than twelve hours.

33. The Directions on the back-panel Drug Facts confirm the Product will adhere for twelve hours because it instructs users to "Use one patch for up to 12 hours" and "Discard patch after single use."



Directions: Adults and children 12 years of age and over:
Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use.
Children under 12 years of age: consult a physician.

34. However, the Product cannot and does not adhere for anywhere close to twelve hours, which renders the Directions misleading, because it assumes it will not have detached by then.

35. Studies have shown the Product is unable to adhere to the skin for more than four hours, often peeling off within minutes of light activity, nowhere near the eight-hour usage time indicated.

36. This inability to adequately adhere during normal use renders the adhesion claim misleading due to the significant disparity between what is promised and what is delivered.

III. MAXIMUM STRENGTH CLAIM IS MISLEADING

37. The representation of “Maximum Strength” and “4% lidocaine” is misleading for multiple reasons.

38. First, prescription lidocaine patches exist on the market that deliver greater amounts of lidocaine to the user.

39. This includes patches with 5% and 1.8% lidocaine, which utilize advanced technology to maximize bioavailability, so even the 1.8% patch will result in greater amounts of lidocaine being absorbed by the body.

40. These patches rely on next-generation adhesive mechanisms that allow them to remain affixed to the wearer’s body for at least twelve hours under normal conditions.¹

41. Second, the FDA cautioned manufacturers of OTC analgesic products against making “maximum strength” claims because higher strength and greater potency versions of such items were available with a prescription.

42. Third, the FDA knew other more concentrated and potent similar products could appear in proximity to those represented as “maximum strength” on store shelves.

43. The result would be that consumers would be misled when other companies labeled their products as “regular strength,” even though both had the same amount of medication and/or active ingredients.

44. Fourth, given that the Product is explicitly compared to Salonpas on its front label,

¹ In studies, this technology maintained a mean adhesion >90% across all time points (0, 3, 6, 9, and 12 h).

“maximum strength” is misleading because the DG Health product contains roughly forty percent less lidocaine, even though they have similar or identical dimensions.

45. Fifth, numerous studies and reports revealed that users of adhesive lidocaine patches using the same technology used by the Product regularly peel off a user’s skin within three to four hours, and sometimes minutes, after being applied.

46. Since, according to the FDA, the actual strength of a lidocaine patch is measured by the “mass of drug relative to the mass of the adhesive per patch” delivered to the target area, these adhesion deficiencies cause the delivery and absorption of lidocaine to be greatly reduced.

47. This inability to adhere for anywhere close to eight hours means the Product cannot deliver the “maximum strength” amount of lidocaine.

IV. DESENSITIZING CLAIMS

48. The Product’s promise to provide “numbing relief” is misleading because it implies its use will completely block and numb nerves and pain receptors, eliminate responses to painful stimuli, and treat neuropathic and musculoskeletal pain, including in the back, spine, shoulders, neck and elbows.

49. The FDA determined that statements about providing “numbing relief” were misleading in the context of transdermal patch delivery systems.

50. This is because consumers, including Plaintiff, associate such statements with medical treatments requiring a prescription and FDA approval.

51. However, the Product is available without a prescription and has not been approved by the FDA.

52. The front label promise to provide “Numbing relief” is inconsistent and contradictory with the Product’s limited approval to “Temporarily relieve[] minor pain,” indicated in the Drug

Facts on the back label.



Jurisdiction and Venue

53. Jurisdiction is based on the Class Action Fairness Act of 2005 (“CAFA”). 28 U.S.C. § 1332(d)(2).

54. The aggregate amount in controversy exceeds \$5 million, including any statutory and punitive damages, exclusive of interest and costs.

55. Plaintiff is a citizen of New York.

56. Defendant is a citizen of Tennessee.

57. The members of the class Plaintiff seeks to represent are more than 100, because the Product has been sold with the representations described here for several years, in thousands of Dollar General stores and online, in the States covered by Plaintiff’s proposed classes.

58. Venue is in this District because Plaintiff resides in this District and a substantial part of the events or omissions giving rise to these claims occurred in this District, including Plaintiff’s purchase and/or use of the Product and awareness and/or experiences of and with the issues described here.

Parties

59. Plaintiff Donna Wright is a citizen of Syracuse, New York, Onondaga County.

60. Defendant Dollar General Corporation is a Tennessee corporation with a principal place of business in Goodlettsville, Tennessee, Davidson County.

61. Dollar General is an American retail corporation that operates a chain of over 18,000 stores throughout the nation, selling everything from outdoor furniture to groceries.

62. Dollar General has almost 600 stores just in New York.

63. It was founded in 1939 with the mission of “Serving Others.”

64. While Dollar General sells leading national brands of OTC products, it also sells a large number of OTC products under its private label DG Health brand.

65. Private label products are made by third-party manufacturers and sold under the name of the retailer, or its sub-brands.

66. Previously referred to as “generic” or “store brand,” private label products have increased in quality, and often are superior to their national brand counterparts.

67. Products under the DG Health brand have an industry-wide reputation for quality and value.

68. In releasing products under the DG Health brand, Defendant’s foremost criteria was high-quality equal to or better than the national brands.

69. Defendant was and is able to get national brands to produce its private label items due its loyal customer base, history of high-quality items and tough negotiating.

70. That DG Health branded products met this high bar was proven by focus groups, which rated them above the name brand equivalents.

71. Private label products generate higher profits because national brands spend significantly more on marketing, contributing to their higher prices.

72. A survey by The Nielsen Co. “found nearly three out of four American consumers believe store brands are good alternatives to national brands, and more than 60 percent consider them to be just as good.”

73. Private label products under the DG Health brand benefit by their association with consumers’ appreciation and awareness of the Dollar General brand as a whole.

74. The development of private label items is a growth area for Dollar General, as it selects only top suppliers to develop and produce DG Health products.

75. As a result of the false and misleading representations, the Product is sold at a premium price, approximately no less than \$4.00 for two patches, excluding tax and sales, higher than similar products represented in a non-misleading way, and higher than it would be sold for absent the misleading representations and omissions.

76. Plaintiff purchased the Product at Dollar General locations in Onondaga County between July 2020 and May 2023, and/or among other times.

77. Plaintiff purchased the Product to provide pain relief to her neck, back, elbows and shoulders.

78. Plaintiff expected the Product to be equal to or greater in quality than the national Salonpas brand, which she was aware of through their ubiquitous advertising.

79. Plaintiff believed “Maximum Strength” meant that no other lidocaine patches were available, either with or without a prescription, that provided more than 4% lidocaine in patch form.

80. Plaintiff saw and read that the Product was “Maximum Strength” containing “4% lidocaine” and that it would deliver this amount of lidocaine, which would provide “Numbing relief” to her “Neck, Shoulder[s], Back, Knee[s] & Elbow[s]” from applying one patch to her body.

81. Plaintiff expected the Product would provide this “Numbing relief” for twelve hours or a small amount of time less than this, because she read “UP TO 12 HOURS” and “Stay-put flexible patch.”

82. Plaintiff relied on the words, terms coloring, descriptions, layout, placement, packaging and/or images on the Product, on the labeling, statements, omissions, claims,

statements, and instructions, made by Defendant or at its directions, in digital, print and/or social media, which accompanied the Product and separately, through in-store, digital, audio, and print marketing.

83. The Product did not adhere to Plaintiff's body for anywhere close to twelve hours, which prevented it from providing even temporary pain relief.

84. The Product did not provide "Numbing relief" to Plaintiff.

85. Plaintiff bought the Product at or exceeding the above-referenced price.

86. Plaintiff paid more for the Product than she would have had she known the representations and omissions were false and misleading, or would not have purchased it.

87. The value of the Product that Plaintiff purchased was materially less than its value as represented by Defendant.

88. Plaintiff chose between Defendant's Product and similarly represented products which did not misrepresent their attributes, features, and/or components.

Class Allegations

89. Plaintiff seeks certification under Fed. R. Civ. P. 23 of the following classes:

New York Class: All persons in the State of New York who purchased the Product during the statutes of limitations for each cause of action alleged; and

Consumer Fraud Multi-State Class: All persons in the States of Idaho, Alaska, Kansas, Iowa, Mississippi and Utah who purchased the Product during the statutes of limitations for each cause of action alleged.

90. Common questions of issues, law, and fact predominate and include whether Defendant's representations were and are misleading and if Plaintiff and class members are entitled to damages.

91. Plaintiff's claims and basis for relief are typical to other members because all were

subjected to the same unfair, misleading, and deceptive representations, omissions, and actions.

92. Plaintiff is an adequate representative because her interests do not conflict with other members.

93. No individual inquiry is necessary since the focus is only on Defendant's practices and the class is definable and ascertainable.

94. Individual actions would risk inconsistent results, be repetitive and are impractical to justify, as the claims are modest relative to the scope of the harm.

95. Plaintiff's counsel is competent and experienced in complex class action litigation and intends to protect class members' interests adequately and fairly.

New York General Business Law ("GBL") §§ 349 and 350
(New York Class)

96. Plaintiff incorporates by reference all preceding paragraphs.

97. Plaintiff believed the Product (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide "Fast acting" "Numbing relief" to her body in multiple places even though it was applied to one location.

98. Defendant's false, misleading and deceptive representations and omissions are material in that they are likely to influence consumer purchasing decisions.

99. Plaintiff would not have purchased the Product or paid as much if the true facts had been known, suffering damages.

Violation of State Consumer Fraud Acts
(Consumer Fraud Multi-State Class)

100. The Consumer Fraud Acts of the States in the Consumer Fraud Multi-State Class are

similar to the consumer protection statute invoked by Plaintiff and prohibit the use of unfair or deceptive business practices in the conduct of commerce.

101. The members of the Consumer Fraud Multi-State Class reserve their rights to assert their consumer protection claims under the Consumer Fraud Acts of the States they represent and/or the consumer protection statute invoked by Plaintiff.

102. Defendant intended that members of the Consumer Fraud Multi-State Class would rely upon its deceptive conduct, which they did, suffering damages.

Breaches of Express Warranty,
Implied Warranty of Merchantability/Fitness for a Particular Purpose
and Magnuson Moss Warranty Act, 15 U.S.C. §§ 2301, *et seq.*

103. The Product was manufactured, identified, marketed and sold by Defendant and expressly and impliedly warranted to Plaintiff that it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide “Fast acting” “Numbing relief” to her body in multiple places even though it was applied to one location.

104. Defendant directly marketed the Product to Plaintiff through its advertisements and marketing, through various forms of media, on the packaging, in print circulars, direct mail, product descriptions distributed to resellers, and targeted digital advertising.

105. Defendant knew the product attributes that potential customers like Plaintiff were seeking and developed its marketing and labeling to directly meet those needs and desires.

106. Defendant’s representations about the Product were conveyed in writing and promised it would be defect-free, and Plaintiff understood this meant it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her

body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide “Fast acting” “Numbing relief” to her body in multiple places even though it was applied to one location.

107. Defendant’s representations affirmed and promised that the Product (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide “Fast acting” “Numbing relief” to her body in multiple places even though it was applied to one location.

108. Defendant described the Product so Plaintiff believed it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide “Fast acting” “Numbing relief” to her body in multiple places even though it was applied to one location, which became part of the basis of the bargain that it would conform to its affirmations and promises.

109. Defendant had a duty to disclose and/or provide non-deceptive descriptions and marketing of the Product.

110. This duty is based on Defendant’s outsized role in the market for this type of Product, a trusted company known for its high-quality DG Health brand.

111. Plaintiff recently became aware of Defendant’s breach of the Product’s warranties.

112. Plaintiff provided or provides notice to Defendant, its agents, representatives, retailers, and their employees that it breached the Product’s warranties.

113. Defendant received notice and should have been aware of these issues due to complaints by third-parties, including regulators, competitors, and consumers, to its main offices,

and by consumers through online forums and/or its website.

114. The Product did not conform to its affirmations of fact and promises due to Defendant's actions.

115. The Product was not merchantable because it was not fit to pass in the trade as advertised, not fit for the ordinary purpose for which it was intended and did not conform to the promises or affirmations of fact made on the packaging, container or label, because it was marketed as if it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide "Fast acting" "Numbing relief" to her body in multiple places even though it was applied to one location.

116. The Product was not merchantable because Defendant had reason to know the particular purpose for which it was bought by Plaintiff, because she expected it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4) would provide "Fast acting" "Numbing relief" to her body in multiple places even though it was applied to one location, and she relied on Defendant's skill and judgment to select or furnish such a suitable product.

Fraud

117. Defendant misrepresented and/or omitted the attributes and qualities of the Product, that it (1) provided the maximum amount of lidocaine in patch form, either with or without a prescription, (2) would adhere to her body for twelve hours or very close to this length of time, (3) was similar in quality, in terms of pain relief and adhesion, to the Salonpas lidocaine patch and (4)

would provide “Fast acting” “Numbing relief” to her body in multiple places even though it was applied to one location.

118. Defendant is one of the leading national retailers with immense resources and a highly skilled regulatory division, capable of ensuring its OTC products were represented truthfully and in accordance with required law and regulations, yet willingly failed to do so.

119. Moreover, the records Defendant is required to maintain, and/or the information inconspicuously disclosed to consumers, provided it with actual and constructive knowledge of the falsity and deception, through statements and omissions.

120. Defendant knew of the issues described here yet did not address them.

121. Defendant’s fraudulent intent is evinced by its knowledge that the Product was not consistent with its representations.

Unjust Enrichment

122. Defendant obtained benefits and monies because the Product was not as represented and expected, to the detriment and impoverishment of Plaintiff and class members, who seek restitution and disgorgement of inequitably obtained profits.

Jury Demand and Prayer for Relief

Plaintiff demands a jury trial on all issues.

WHEREFORE, Plaintiff prays for judgment:

1. Declaring this a proper class action, certifying Plaintiff as representative and the undersigned as counsel for the class;
2. Awarding monetary, statutory and/or punitive damages and interest;
3. Awarding costs and expenses, including reasonable fees for Plaintiff’s attorneys and experts; and

4. Other and further relief as the Court deems just and proper.

Dated: May 30, 2023

Respectfully submitted,

/s/Spencer Sheehan

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